Supreme Court, U.S.
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NO. 93-1045

IN THE SUPREME COURT OF THE
UNITED STATES

OCTOBER TERM, 1993

JEWISH MEMORIAL HOSPITAL, ET AL.,

Petitioners,

v.

COMMONWEALTH OF MASSACHUSETTS,
ET AL.,

Respondents.

On Petition For Writ of Certiorari
To The Supreme Judicial Court
Of Massachusetts

PETITIONERS' REPLY BRIEF TO RESPONDENTS' BRIEF IN OPPOSITION

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Pursuant to Supreme Court Rule 15.6, the Petitioners submit this reply brief in response to the "Respondents' Brief in Opposition."

REASONS FOR GRANTING THE PETITION

I. THIS COURT HAS JURISDICTION UNDER 28 U.S.C. §1257(a) BECAUSE THE DECISION OF THE SUPREME JUDICIAL COURT IS FINAL AS TO THE FEDERAL ISSUE RAISED.

Review is being sought of the following provision of the declaratory judgment which was affirmed by the Supreme Judicial Court: "The Department of Public Welfare's regulations set forth in 106 C.M.R. §§435.401-410 as amended effective March 1, 1991... do not violate the requirements of 42 U.S.C. §1396b(i)(4),..." R.A. 351.[1] The Respondents point to no other federal issues related to preadmission review that are to be considered by the Superior Court on remand.

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[1] References to the record appendix filed with the Supreme Judicial Court are denoted as "R.A. __".

In Cox Broadcasting Corp. v. Cohn, 420 U.S. 469 (1975), this Court noted four situations in which the adjudication of a federal issue in a case by the highest available state court was reviewable in this Court even though further state court proceedings were to take place. This case falls within two of the exceptions. The issue of federal law has been decided by the Supreme Judicial Court. Any additional proceedings in State Superior Court would not require a decision on other federal questions concerning preadmission review that might require review at a later date. Cox Broadcasting Corp., 420 U.S. at 480, citing Radio Station WOW v. Johnson, 326 U.S. 120, 127 (1945).

To the extent that any amendment to the judgment could affect the

federal issue presented in the Petition for Writ of Certiorari ("the Petition"), the Respondents have not suggested that the Supreme Judicial Court's affirmance of the State Superior Court's declaration that the regulations set forth in 106 C.M.R. §§435.401-410 do not violate the requirements of 42 U.S.C. §1396b(i)(4), makes the outcome of any amendment on this issue anything but preordained.[2] Cox Broadcasting Corp., supra, at 479. For purposes of this Court's jurisdiction, the

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[2] For example, the Supreme Judicial Court noted that the lawfulness of other, later numbered sections of the Department's regulations on the same general subject is not addressed in the judgment. Jewish Memorial Hospital, 416 Mass. 132, 134, 617 N.E.2d 598, 600 (1993).

decision of the Supreme Judicial Court is final as to the federal issue raised.

II. THE PETITION PRESENTS AN IMPORTANT FEDERAL ISSUE.

The issue is whether Massachusetts' preadmission screening and level of care regulations conflict with federal utilization review requirements prescribed by 42 U.S.C. §1396b(i)(4). Congress directed that utilization review for Medicaid patients (which includes preadmission review) be conducted using the same procedures and standards used for Medicare patients. 42 U.S.C. §1396b(i)(4). By establishing different procedures and standards than those required by the Social Security Act, the Massachusetts preadmission review

program and level of care criteria conflict with this Congressional mandate.[3]

Resolution of the federal question is important because at present Petitioner hospitals and physicians are placed in an untenable position when a hospital's utilization review committee concludes that hospitalization of a Medicaid patient is medically necessary but Massachusetts preadmission review standards dictate

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[3] The fact that the Massachusetts requirements are different from the Medicare requirements is confirmed by the Respondents. The Respondents state that certain amendments were made to bring Massachusetts requirements "intc closer conformity with criteria applicable under the Medicare program". Brief at 12. Thus, it is undisputed that Massachusetts criteria are not the same as the Medicare criteria.

that hospitalization is not "appropriate for reimbursement purposes". Jewish Memorial Hospital, 416 Mass. at 136, 617 N.E.2d at 602. The Petitioners must either admit the patient and not be reimbursed for care determined to be medically necessary at a hospital level by the utilization review committee or refuse to admit the patient and be exposed to malpractice claims.

The distinction drawn by the Massachusetts Supreme Judicial Court and by the Respondents between care which is "medically necessary" and care for which reimbursement is appropriate is not permitted under federal law. Medical care which is medically necessary and included in the state plan must be covered.

In their opposition, Respondents now claim that the distinction is

between "placement" and "care". Brief at 29. Placement and care cannot be neatly compartmentalized as suggested by the Respondents. The type of care a patient receives is dictated by the facility in which the patient is placed. It is axiomatic that the same level of care and medical resources are not available in a hospital and a nursing home.

As a result of the conflict between the federal requirements and the Massachusetts regulations, Medicaid recipients are placed in a Catch-22 dilemma. Care may be determined medically necessary under federal utilization review standards but Massachusetts may still conclude that placement is not reimbursable under state standards. Congress sought to avoid just such a dilemma by directing that utilization review

be conducted using the same standards for Medicare and Medicaid.

The conflict between the federal statutory and regulatory requirements and the Massachusetts regulations implicates important concerns and warrants granting certiorari.[4] See Kolovrat v. Oregon, 366 U.S. 187, 191 (1961) (certiorari granted where state statute conflicted with federal statute notwithstanding no conflict of the circuits, and no conflict with another state's highest court). In Kolovrat, as here there was simply a claim that the state court was wrong.

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[4] Respondents' reliance on In Re Woods, 143 U.S. 202, 206 (1892) is misplaced. The questions presented in that case involved solely state law and common law. Certiorari had been sought in order to "avert diversity of judgments..." Id.

This Court required that the state policy "give way" to the federal policy. Id. at 190. Similarly, in this case, the Massachusetts regulations conflict with federal law and must give way to the federal requirements.[5]

III. THE SUPREME JUDICIAL COURT ERRED IN HOLDING THAT THE REGULATIONS ARE CONSISTENT WITH THE SOCIAL SECURITY ACT.

A. The Health Care Financing Administration Has Not Made A Determination That the Regulations Are Consistent With Federal Law.

The Respondents argue that the Health Care Financing Administration (HCFA) has made a determination that the regulations are consistent with federal law. A December 21, 1990 letter from HCFA's Associate Regional

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[5] The phrase "a statute of any state" in 28 U.S.C. §1257 includes a regulation. See Lathrop v. Donohue, 367 U.S. 820, 825 (1961).

Administrator relied upon by the Respondents is not an official ruling, interpretation or advisory opinion issued by the Administrator of HCFA. Even if it were, an interpretive ruling by HCFA is not controlling on the courts. Daughters of Miriam Center for the Aged v. Mathews, 590 F.2d 1250, 1263 (3d Cir. 1978). The letter does not represent a federal finding that the regulations conform to federal law. Rather, the letter merely represents HCFA's acceptance of the Respondents' assurances on this issue. Under the Medicaid program, federal officials routinely accept assurances provided by state officials. For example, in the context of reimbursement, they do not require a State to submit findings or underlying data to determine the truth or validity of

those assurances. Wilder v. Virginia Hospital Ass'n, 496 U.S. 498, 508 (1990).

Under the Medicaid program, the State may not deviate from the utilization review standards and procedures prescribed by the Medicare program unless the State demonstrates to the Secretary of Health and Human Services that it has developed utilization review procedures which are superior in their effectiveness and the Secretary waives the requirements of §1396b(i)(4). 42 U.S.C. §1396b(i)(4). The record indicates that the State did not obtain a waiver of federal utilization review requirements in the manner provided for by 42 U.S.C. §1396n(b) or demonstrate to HCFA that it has developed a superior method. The State admitted as much in its

answer to the complaint. R.A. 156. The HCFA letter cited by the Respondents does not state that preadmission review is not part of utilization review and does not address the Respondents' failure to obtain a waiver as required by federal law.

Accordingly, the Court should look behind the assurances provided by the State to determine whether the regulations are consistent with federal law, specifically, 42 U.S.C. §1396b(i)(4).

B. <u>There is No Federal Regulation Prescribing Preadmission Screening Review Requirements For Medicare and Medicaid</u>.

The Respondents refer to Massachusetts Medicaid preadmission screening programs for acute care hospitals and child psychiatric

hospitals in an effort to lend validity to the preadmission screening program for chronic disease and rehabilitation hospitals. Brief, p. 7. The validity of these other programs was not raised by the Respondents and cannot transform the illegal preadmission regulations at issue here into regulations that comply with federal law.

The Respondents also refer to a preadmission screening program for Medicare and Medicaid which HCFA began to institute in 1975, citing American Medical Association v. Weinberger, 522 F.2d 921 (7th Cir. 1975) and 42 C.F.R. Ch. IV (10-1-89 Edition), at 250-1 & n. 1. Brief, p. 7 n. 3. Although they point out the Weinberger case was dismissed on the condition that the admission review requirements be revised, they

fail to amplify that to date the admission review requirements contained in 42 C.F.R. Ch. IV are still in the process of being revised. Thus, currently, the federal regulations the Respondents point to remain ineffective. See 42 C.F.R. Ch. IV (10-1-92 Edition) at 274 n. 1.

In any event, the lawfulness of preadmission screening under the Medicare and Medicaid programs is not the issue presented for review. Rather, the issue is whether the regulations governing the Massachusetts preadmission screening program for chronic disease and rehabilitation hospitals violate 42 U.S.C. §1396b(i)(4) by applying procedures and standards which are

inconsistent with those applied under the Medicare program.[6]

C. The Preadmission Screening Program and Level of Care Criteria Conflict With Utilization Review Standards and Procedures Applied Under the Medicare Program.

The Respondents' attempt to convince this Court that the level of care criteria are consistent with the standards applied under the Medicare program is misleading. First, contrary to the Respondents' assertion, Brief,

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[6] The fact that 106 CMR §435.401(B)(3) provides that "a final determination of non-coverage will be made only by a physician" misses the point. The physician is constrained by the regulations to make his/her decision based on level of care criteria which conflict with the standards applied under the Medicare program.

p. 3, the affidavits[7] submitted by the Petitioners do not state that Peer Review Organizations ("PROs") "base" their determinations of medical necessity of inpatient hospital admissions on the application of the Adult Appropriateness Evaluation Protocol ("AEP"). Rather, the affidavits attest that the AEP is merely "one component" of the Medicare utilization review process. (R.A. 93,

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[7] Contrary to the Respondents' assertion, Brief p. 4, n. 2, the physicians' affidavits are based on factual matters within the affiants' knowledge. Seven physicians attested that the hospitals at which they practiced followed the Medicare utilization review process. R.A. 92, 98, 107, 118, 128, 138, 142. Six physicians were on their hospitals' utilization review committees; the other was past president of his hospital's utilization review committee. Id. In addition, two of the physicians served as physician reviewers for MassPRO, the federally designated Massachusetts Peer Review Organization. 42 U.S.C. 1320c-2(b)(2). R.A. 118, 128.

99, 108, 119, 129, 139, 142, 180). Issues regarding physician assessment of patient safety, medical instability, quality assurance and availability of resources in the community are other components. Id.[8]

The Respondents' reliance on articles in medical journals is misplaced. The articles describe the use of the AEP to determine the appropriateness of an acute hospital admission not a chronic hospital admission. This is because the AEP has not been found to be a valid instrument by which to measure the need for chronic hospital level of care. R.A. 212.

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[8] An affidavit submitted by Mehbooba Anwar, M.D., who is board certified in utilization review and quality assurance and serves as a physician reviewer for MassPRO, which describes the use of the AEP in the utilization review process is reproduced in the Appendix (infra, pp. A-1 - A-12).

Second, the Respondents' reference to §435.409(A) (1) and (2) underscores the problem which arises when a state Medicaid program fails to follow federal Medicare utilization review requirements. Under §435.409(A)(1)(c) patients who do not require "daily or more frequent physician supervision" or "the constant availability of medical services and equipment ordinarily available only in a hospital" are disqualified from hospital admission. There are some patients who may not require daily or more frequent supervision but for whom hospitalization would be deemed medically necessary under Medicare standards. R.A. 140. However, if these patients are admitted to nursing homes, they will receive only monthly physician visits absent an emergency. See 130 CMR 433.416(B) (payment for physician visits to

Medicaid patients in nursing homes limited to one visit per month). Appendix, infra, p. A-13.

Finally, the Respondents refer to the so-called "catch-all alternative" under §435.409(A)(2). Brief, pp. 17-18. The Respondents fail to point out that whether a recipient falls within the "catch-all alternative" is to be determined by "the clinical staff of the Department's medical case management program", not the hospital's utilization review committee.

CONCLUSION

For the foregoing reasons and the reasons stated in the Petition for a Writ of Certiorari, the Petition should be granted.

Respectfully submitted,

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Dated: February 1, 1994

APPENDIX

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS. SUPERIOR COURT
DEPARTMENT OF THE
TRIAL COURT

CIVIL ACTION
NO. 2553-93

JEWISH MEMORIAL HOSPITAL, et al.

Plaintiffs

vs.

DEPARTMENT OF PUBLIC WELFARE, et al.

Defendants

AFFIDAVIT OF
MEHBOOBA ANWAR, M.D. IN
SUPPORT OF PRELIMINARY INJUNCTION

I, Mehbooba Anwar, M.D., hereby depose and state that the following is true and based upon my personal knowledge.

1. I am a physician duly licensed to practice medicine within the Commonwealth of Massachusetts. I

currently serve as Medical Director of Massachusetts Respiratory Hospital and am responsible for medical care provided at the Hospital. I also serve as the Chairperson of the Hospital's Utilization Review Committee. I am board certified in utilization and quality assurance. I also serve as a Physician Reviewer for "MASS PRO" a federally established program for utilization review and quality assurance for medical care provided for Medicare patients.

2. I have reviewed the regulations governing the medical necessity of services provided by chronic disease and rehabilitation hospitals scheduled to be implemented on December 1, 1990 by the Department of Public Welfare. Attached hereto is [sic] Exhibit A is a true and accurate copy of that draft.

3. Massachusetts Respiratory Hospital follows the Medicare guidelines of the utilization review process to determine the medical necessity of patient admissions and the appropriateness, including safety of patient discharges. Similar process is followed for Medicaid patients. The Adult Appropriateness Evaluation Protocol ("AEP") is used as one of the components on admission by utilization review nurses to approve the admission as meeting the criteria but when and if "AEP" criteria are not met the care [sic] is reviewed by a U/R physician for the patient's medical condition, safety, quality assurance and availability of resources within the community prior to making a decision for denial. The attending physician and U/R physician takes unto consideration the potential for medical instability and for safety

and therefore may override "AEP" criteria. It is the responsibility of the attending physician and U/R physicians to apply their experience and medical knowledge in determining any potential for harm. The Department of Public Welfare's strict application of "AEP" criteria without incorporation of medical judgements will lead to admission denials and subject such patients to discharge procedures with serious potential for harm to patients due to inappropriate management.

4. Section 435.409 of the proposed regulations ignores the fact that under Medicare, the "AEP" may not be used by nurses, physicians or anyone else to deny admissions. Only a physician may deny an admission. Furthermore, under the Medicare process, only a peer of the attending physician may deny payment for an admission deemed

appropriate by the attending physician and such a denial may take place only after two levels of review have been provided, and even then additional appeal rights exist. The notice and appeal provisions set forth under Section 435.409(B) of the proposed regulations do not provide for such review. There is no requirement that the physician reviewer be a true peer of the attending physician.

5. I understand that the proposed regulations at 106 CMR 435.409 also apply to rehabilitation units in chronic disease hospitals. However, the "AEP" does not have rehabilitation guidelines. Therefore, it is inappropriate (and makes no sense) to apply the "AEP" to rehabilitation patients.

6. I have read 106 CMR 435.411 which requires that a review of each admission and continued stay be

conducted in accordance with Sections 435.409 and 435.410. What this means to me is that the "AEP" applies to patients at chronic disease and rehabilitation hospitals not only on admissions but also on continued stay review and on conversion. Under the Medicare program, the "AEP" is not used for conversions and is only one of a number of components used for continued stay review. In my experience at Massachusetts Respiratory Hospital, at any given point in time after admission, approximately 50% of the patients might not meet the "AEP" on a continual basis. Moreover, in my experience as a Mass Pro Review Physician, patients do not meet the "AEP" on a continual basis. The DPW is therefore proposing a level of care standard for chronic disease and rehabilitation hospitals that is even more stringent than the level of care

standard applied to acute hospitals. If implemented the regulation will directly interfere with my ability to admit and continue to treat patients.

7. The DPW's proposed regulations direct hospital physicians, including myself, to use the "AEP" to disqualify patients from continued hospital level of care. Patients not meeting the "AEP" are subject to discharge. Under the DPW's proposed regulations, I am also directed to deny admission and therefore, hospital services, to any patient who does not meet the "AEP".

8. One facet of the proposed regulation (106 CMR 435.409(A)(3)) requires that in order for hospital care to be medically necessary a patient must require daily physician services. By regulation 106 CMR 433.416(B), the DPW limits payment for physician visits to nursing home patients to one visit per

month, except in cases of an emergency. Therefore, patients at the Massachusetts Respiratory Hospital who are disqualified from hospital care because they do not meet the AEP on a continual basis (and/or do not require daily physician services) will generally only receive monthly physician visits in a nursing home. Various classes of patients subject to transfer clearly require more than monthly physician visits and may die before a nursing home staff knows the patient is in a medical crisis. Examples of these patients are: those who suffer from congestive heart failure with changes in weight due to fluid retention; those who have brittle diabetes with blood sugars varying from 50 to 400. Such patients are likely to have other unstable medical conditions and to require ongoing physician monitoring of multiple medications and

metabolic abnormalities. If such patients were discharged to nursing homes, they would predictably medically deteriorate rapidly, and among other things, experience pain, develop pneumonia, urinary infections and infectious sores. It is a medical fact that the foregoing will increase patient morbidity.

9. There are also classes of patients who would not meet the AEP on a continual basis who should not be discharged to nursing homes because the care which they require is not available there. These patients include those requiring IV fluids on a regular basis, those requiring inhaled bronchodilator treatment, and those whose pulmonary care requires medication and tracheostomy care with frequent suctioning. In my experience none of

these services are customarily and usually available in nursing homes.

10. Patients suffering from severe chronic obstructive pulmonary diseases require close medical and nursing monitoring to prevent deterioration and immediate availability of respiratory therapists to provide inhaled bronchodilator treatments. Patients with tracheostomies require frequent suctioning and assessment. The above types of patients may not meet "AEP" criteria on a continual basis. Therefore discharging these patients to inappropriate settings will cause deterioration and death. In my experience these services are not available in nursing homes. Under the Medicare program these patients meet the criteria of covered hospital level of care.

11. In view of the foregoing, the Department of Public Welfare's proposed regulations demand me to discriminate against Medicaid patients, which in my judgment interferes with my right to practice medicine in a standard and safe manner.

12. The Department of Public Welfare proposed a contract to implement the regulation which requires the Hospital to assist in hearings should a patient object to an application of the AEP. This means that Hospital medical staff would be required to testify against patients including those seeking admission. I object to this requirement. The medical staff cannot be placed in the position of acting contrary to the best interests of patients.

Signed and sworn to under the pains and penalties of perjury.

_____

Mehbooba Anwar, M.D.

Dated: November 21, 1990

433.416: Nursing Facility Visits: Service Limitations

(B) Service Limitations. Payment for a visit by a physician to recipients in nursing facilities or rest homes is limited to one visit per recipient per month, except in an emergency. Any medically necessary care required for the follow-up of a condition during the month must be billed as subsequent nursing facility care.